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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,302	01/30/2002	Randall T. Lashinski	MITRAL.001CP2	2373

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,302

Applicant(s)

LASHINSKI ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 9, 10, 15, 16 and 36 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-32, 38 and 39 is/are allowed.
- 6) ☒ Claim(s) 1-3, 11-14, 17-19, 33-35 and 37 is/are rejected.
- 7) ☒ Claim(s) 4 and 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5-7, 9, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species (1)(d), (2)(c) and (3)(a) in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 5-7, 9, 10, 15, 16 and 36 have been withdrawn from consideration. The claims being considered for further examination on the merits are 1-4, 8, 11-14, 17-35 and 37-39.

Priority

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. While the first sentence of the specification does refer to the application as being a CIP of 09/774,869, it does not then further state that 09/744,869 is a CIP of 09/494,233, filed on 1/31/00 and now U.S. Patent No. 6,402,781. The declaration indicates that the current application is claiming benefit of both 09/744,869 and 09/494,233, so the specification must be corrected to reflect this.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "114" has been used to designate both "body 114" (mentioned in [0089] and shown in Figures 7-9) and "tissue contacting surface 114" (mentioned in [0106] and shown in Figure 5). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Applicant is reminded that any changes made to the reference numbers in the specification must also be changed in the respective figures and vice versa.
4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "15F-15F" is not shown in Figure 15E. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "218" shown in Figure 11A is not mentioned in the specification. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
6. The drawings are objected to because it appears from [0161], line 3 that "402" in Figure 20 should be changed to --408--. A proposed drawing correction or corrected drawings are

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required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the deflectable implant further comprising a second deflection wire, secured at a second point of attachment in between the first point of attachment and the proximal end (as required by claim 37) must be shown in addition to the lock at the proximal end of the housing for engaging the first deflection wire (as required by claim 33) or the feature(s) canceled from the claim(s). No new matter should be entered. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is no support in the specification for the apparatus having an axial length of no more than about 10cm, as required by claim 18. In [0081], line 2, and [0093], line 2, the axial length is given to be “about 2cm to about 10cm” and in [0163], line 6, the length is given to be “within the range from about 5 cm to about 15 cm”. Also there is no support in the specification for the maximum cross sectional dimension through the apparatus being “no more than about 10mm”, as required by claim 19. In [0093], line 9, the cross sectional dimension is given as “no more than about 15mm² and preferably no more than about 10mm²”. Because these

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claim limitations were originally presented at the time of filing, they should be included into the written specification.

9. The disclosure is objected to because of the following informalities:

- a) A brief description of FIG. 2A is missing.
- b) In [0050], it appears that "Figure E" should be changed to --Figure 15E--.
- c) In [0139], line 2, it appears that "Figure 2H" should be changed to --Figure 15H--.
- d) In [0146], line 9, it appears that "Figure 15B" should be changed to --Figure 18B--.
- e) In [0136], line 10, it appears that "forming element 320" should be changed to --forming elements 365, 375, 385--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-35 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 33 recites the limitation "the housing longitudinal axis" in line 12. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 11-14 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Solem et al. (USPN 6,210,432 as cited in applicant's IDS).

Solem et al. discloses an apparatus for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 1. See Figures 12 and 13 and columns 4-5, lines 56-4 for an elongate body (8") having proximal and distal end regions each dimensioned to reside completely within the vascular system. The elongate body (8") comprises a tube (combination of three stent sections) having a plurality of transverse slots (spaces between the wires forming each stent section) and is movable from a first configuration for transluminal delivery to at least a portion of the coronary sinus to a second configuration for remodeling the mitral valve annulus proximate the coronary sinus. A forming element (27) is attached to the elongate body (8") for manipulating the elongate body from the first transluminal configuration to the second remodeling configuration.

Claim 11, see column 5, lines 14-15 for a coating on the body.

Claim 12, see columns 4-5, lines 62-4 for the apparatus being movable from the implantation configuration to the remodeling configuration in response to proximal retraction of the forming element.

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With respect to claim 13, because the forming element (27) is attached to the distal stent section (23), distal advancement of the forming element will separate distal stent section (23) from stent sections (24, 25), thereby decreasing the radius of curvature of the elongate body. A straighter configuration can be a remodeling configuration. Therefore, the apparatus is certainly “movable” (capable of being moved) from the implantation configuration to the remodeling configuration in response to distal advancement of the forming element.

Claims 14 and 17, see column 4, lines 23-25 for an anchor comprising a barb for retaining the apparatus at the deployment site within a vessel.

With respect to claims 18 and 19, because of the dimensions of the coronary sinus, it is inherent that the axial length and cross-sectional dimension of the apparatus will not exceed the values required by claims 18 and 19.

14. Claims 33-35 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Gabbay (USPN 6,368,348).

Gabbay discloses a deflectable implant with all the elements of claim 33. See Figures 12A-12B for the deflectable device comprising an elongate flexible housing (rolled 202) having proximal (210) and distal (208) ends and a central lumen extending therebetween, the housing being flexible in a lateral direction (Figure 13). There is an axially extending column strength support (200) in the implant and at least a first deflection wire (212) having proximal and distal ends extending along the housing and being secured at a first point of attachment with respect to a distal portion of the column strength support (see column 7, lines 46-55). See Figures 15A-15C for a lock (410) for engaging the deflection wire to enable the deflection wire (212) to retain

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a curve in the housing, wherein the axis of at least a portion of the housing is displaced laterally in response to axial displacement of the deflection wire, thereby causing the distal end of the housing to bend to form a curve in the housing (see column 9, lines 58-67).

Claim 34, see column 7, lines 49-51 for support extending within about 2 cm.

Claim 35, see Figure 12A for the support (200) comprising a portion of the housing wall.

Claim 37, see Figure 12A for a second deflection wire (214).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-3, 12-14, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (USPN 6,569,198 as cited in applicant's IDS) in view of Paskar (USPN 5,304,131).

Wilson et al. discloses a mitral valve annuloplasty prosthetic device with all the elements of claim 1, but is silent to the tubular body having a plurality of transverse slots therein to permit flexing in at least one plane. See Figure 2 for an elongate tubular body (12), a forming element (48) attached to the elongate body for manipulating the body from the first transluminal configuration to the second remodeling configuration. Paskar teaches forming a plurality of transverse slots (75, 77, 79) in a tubular body in order to form a predetermined region of weakness. As a result, tension being applied to a wire attached to the distal end of the tubular

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body bends in the direction of the predetermined weakness. See column 7, lines 51-64. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Paskar to modify the device of Wilson et al. by including a plurality of slots in the tubular body. The slots will provide the body with a predetermined region of weakness so that when the device is deployed from the catheter, the body will bend only in the direction of the predetermined weakness, towards the mitral valve annulus. This will aid in the proper orientation of the device within the coronary sinus.

Claim 2, see Figure 5 for the elongate body forming an arc when in the remodeling configuration, which may be done by changing the shape of the slots.

With respect to claims 3, 18 and 19, because of the radius of curvature and dimensions of the coronary sinus, it is inherent that the best fit constant radius curve, axial length and cross-sectional dimension of the apparatus will not exceed the values required by these claims.

Claims 12 and 13, see column 6, lines 31-33 and column 7, lines 55-57 for proximal retraction or distal advancement.

Claim 14, see Figures 4a-4b for anchor (72).

17. Claims 11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. in view of Paskar as applied to claim 1 above, and further in view of Solem et al.

Wilson et al. and Paskar disclose a mitral valve annuloplasty prosthetic device with all the elements of claim 1, but is silent to the additional limitation of a coating on the body, as required by claim 11. Solem et al. teaches a mitral valve annuloplasty device wherein a coating of heparin is applied to the device in order to avoid thrombosis in the coronary sinus, and thus

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reduce the need for aspirin, ticlopedine or anticoagulant therapy. See column 5, lines 14-17. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Solem et al. to modify the device of Wilson et al. and Paskar by including a coating, specifically of heparin, to the body in order to avoid thrombosis in the coronary sinus, and thus reduce the need for aspirin, ticlopedine or anticoagulant therapy.

Wilson et al. and Paskar are also silent to the additional limitation of the anchor comprising at least one barb for piercing the wall of the vessel, as required by claim 17. Solem et al. teaches an anchor comprising at least one barb for piercing the wall of the vessel in order to retain the device within the vessel at the desired location. See column 4, lines 23-25. While the spring coil mechanism of Wilson et al. and the barbs of Solem et al. serve the same purpose of anchoring, the barbs are much more simple than the coil mechanism. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention, therefore, to look to the teachings of Solem et al. and replace the coil mechanism of Wilson et al. with the barbs of Solem et al. in order to reduce the complexity of the device.

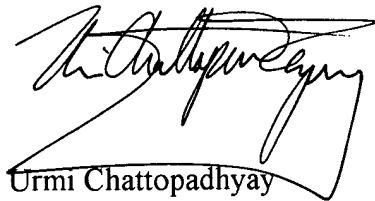
Allowable Subject Matter

18. Claims 20-32, 38 and 39 are allowed.
19. Claims 4 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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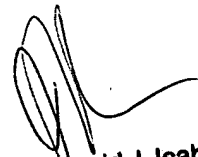
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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David J. Isabella
Patent Examiner
David J. Isabella